



Baptist
HEALTH

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Little Rock, AR 72205-7299
501 202-2000

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August 26, 1999

Documents Branch
Food & Drug Administration
5630 Fishers Lane #1061
Rockville, MD 20852

Dear Gentlemen:

Baptist Health is a non-profit five hospital, integrated health system with well over 6,000 employees and 1,000 physicians on medical staff. In addition to 1,270 licensed beds, Baptist Health supports a 400 resident retirement center, a school of nursing and allied health, a physician organization, an HMO joint venture and a 14 hospital affiliate network.

On behalf of Baptist Health, I am writing you in regards to a draft guidance document (HFA-305) that proposes health providers initiate a HCV Lookback Program using a 1990 HCV test. The draft document also proposes providers "search historical records dating back indefinitely to the extent that electronics or other readily retrievable records exist."

As you are aware, the most recent requirement of a HCV Lookback (1992 test) required a review going back to January 1988, not an indefinite period of time. This particular Lookback produced negligible results in part because many former patients received blood transfusions prior our initiation of an automated filing system and in part because many were unable to be located. In fact, at Baptist Medical Center, we have only been able to locate 10 of the 55 patients designated by the Red Cross as those who should be contacted.

We continue to attempt to comply with the 1992 Lookback expending approximately 6 hours a week in what is arguably negligible results. In addition, creating unnecessary fear among patients is a negative result of this effort. I encourage you to thoroughly evaluate weighing the benefits to the patient when considering expansion of another lookback.

The FDA should consider whether patients that visit a hospital or physician's office who reveal a blood transfusion in their past be tested for Hepatitis C. Simply stated, there has to be a better and more sensitive way to address this issue rather than imposing open ended mandates that produce negligible results.

Thank you for your consideration of the above.

Sincerely,

Russell D. Harrington, Jr., FACHE
President

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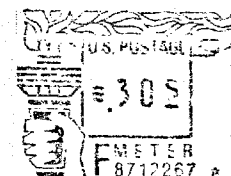
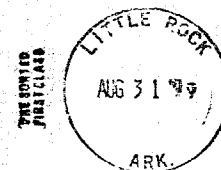
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